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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,580	03/17/2004	Jerome C. Bressi	SYR-HDAC-5005-C2	6189

32793 7590 05/29/2007  
TAKEDA SAN DIEGO, INC.  
10410 SCIENCE CENTER DRIVE  
SAN DIEGO, CA 92121

EXAMINER
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CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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05/29/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/803,580	<b>Applicant(s)</b> BRESSI ET AL.	
	<b>Examiner</b> Celia Chang	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 109-116, 118-128, 130-140 and 143-177 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 109-116, 118-128, 130-140 and 143-177 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Amendment and response filed by applicants dated Mar. 15, 2007 have been entered and considered carefully.

Claims 1-108, 117, 129, 141-142, have been canceled. Claims 144-177 have been added. Claims the members of claim 109-116, 118-128, 130-140, 143 -177 are pending.

2. The rejection of claims 109, 111, 112, 117, 119, 121, 122-124, 129, 131, 133-136, 141 and 143 under 35 USC 112 second paragraph for the language "comprising" is dropped in view of the amendment of the claims.

3. The rejection of claims 109, 112, 121, 124, 133 and 136 under 35 USC 112 second paragraph is dropped for the scope of "M" in view of the amendment.

The rejection for E or Z is dropped in view of the amendment.

The rejection for *a substituent that is convertible in vivo to hydrogen* is maintained.

Please note that there is no antecedent basis for this term in the specification (p.50) for R<sup>14</sup>. The insertion of this term into the base claims finds no antecedent basis as to what is the scope of this term. The term in claims 112 or 136 which are dependent claims, can only be explicitly pointed out by naming the members of claim 109 that can be converted to hydrogen in vivo. The insertion constitutes broadening of the scope and may be considered being new matter since it is unclear what does it mean because no antecedent basis or description for such scope was found in the specification. This term employed in the dependent claims 112 and 136 as originally filed can only mean the members of claim 109 as originally filed that can be converted to hydrogen in vivo.

4. The rejection of claims 109 and 121 under 35 USC 112 first paragraph for lacking enablement other than C2-C10 is maintained for reason of record.

No description to the recited linker which broadly reads on peroxide, disulfides as well as using the formylphenacyl acetic acid, furanyl etc. material to form the linker was found in the specification. Nowhere in the literature that such link will produce compounds that will have a

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commonality in biological activity as the C2-C10 compounds. None of the recitation of material by applicants Exhibits A-D indicated any biological activity nor any support of an art recognized Markush variation as the exemplified C2-C10 compounds as histone deacetylase inhibiting activity. The mere provision of the "language" does not constitute enablement as it was clearly explained in the previous office action.

5. The rejection of claims 109-112, 115, 121-124 under 35 USC 103(a) over Vourloumis in view of CA 139 is dropped in view of the amendment clearly limiting the M variable to the amended scope in the claims.

6. The provisional rejection of claims 109-116, 118-128, 130-140, 143 under the judicially created doctrine of obvious double patenting over the pending claims of copending SN 10/803,575 is now applicable to newly added claims 144-177 and maintained for reason of record.

No acceptable terminal disclaimer was filed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
May 24, 2007

A handwritten signature in black ink, appearing to read 'C. Chang'.

*Celia Chang*  
*Primary Examiner*  
*Art Unit 1625*